

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appln. No.	:	09/924,320	Confirmation No.:	3586
Applicant	:	HUANG, Mark		
Filed	:	August 7, 2001		
TC/A.U.	:	3733		
Examiner	:	REIMERS, Annette R.		
Docket No.	:	P893		
Customer No.	:	28390		
Title	:	BALLOON STENT ASSEMBLY SYSTEM AND METHOD		

Mail Stop AMENDMENT
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

AMENDMENT

Sir:

In response to the Office Action mailed February 14, 2007, please amend the above-identified application as set forth below.

Amendments to the Claims are reflected in the listing of claims which begin on page 2 of this paper.

Remarks/Arguments begin on page 6 of this paper.

Amendment to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

Claim 1 (currently amended): An apparatus for treating a vascular condition comprising:

a balloon including an outer first layer and an inner second layer, the outer first layer covering only a limited portion of the inner second layer; and

a stent disposed on the outer first layer of the balloon;

wherein the outer first layer flows into gaps formed in the stent when the ~~balloon stent assembly~~ apparatus is heated to a predetermined temperature, and retains the stent on the balloon during intravascular movement and the inner second layer does not flow into the gaps.

Claim 2 (previously presented): The apparatus of claim 1 wherein the predetermined temperature comprises a temperature range of about 50 to 70 degrees Celsius.

Claim 3 (canceled).

Claim 4 (previously presented): The apparatus of claim 1 wherein the outer layer and the inner layer comprise a co-extruded laminate.

Claim 5 (previously presented): The apparatus of claim 1 wherein the outer layer comprises a tie layer material.

Claim 6 (previously presented): The apparatus of claim 1 wherein the outer layer comprises a functionalized material.

Claim 7 (previously presented): The apparatus of claim 6 wherein the functionalized material comprises at least one material selected from a group consisting of: polyethylene, ethylene-vinyl-acetate, acrylate, Bynel[®], and Plexar[®].

Claim 8 (previously presented): The system of claim 6 wherein the functionalized material is not tacky at temperatures below the predetermined temperature.

Claim 9 (previously presented): A balloon stent assembly system comprising:
a balloon including at least one non-tacky outer layer and at least one inner layer,
the non-tacky outer layer covering only a limited portion of the at least one inner second layer;
and

a stent disposed on the outer layer;
wherein when the balloon is heated at a predetermined temperature the outer layer
flows into gaps formed in the stent while the inner layer does not flow.

Claim 10 (previously presented): The system of claim 9 wherein the stent covers
at least 55 percent of the outer layer.

Claim 11 (original): The system of claim 10 wherein the balloon provides at least
200 gram force of a stent retention force.

Claim 12 (previously presented): The system of claim 9 wherein the stent covers
at least 70 percent of the outer layer.

Claim 13 (original): The system of claim 12 wherein the balloon provides at least
300 gram force of a stent retention force.

Claim 14 (previously presented): The system of claim 9 wherein the stent covers
at least 90 percent of the outer layer.

Claim 15 (original): The system of claim 14 wherein the balloon provides at least
90 gram force of a stent retention force.

Claim 16 (original): The system of claim 9 wherein the predetermined
temperature comprises a temperatures range of about 50 to 70 degrees Celsius.

Claim 17 (original): The system of claim 9 wherein the outer layer and the inner
layer comprise a co-extruded laminate.

Claim 18 (original): The system of claim 9 wherein the outer layer comprises a
tie layer material.

Claim 19 (original): The system of claim 9 wherein the outer layer comprises a first material and the inner layer comprises a second material different from the first material.

Claim 20 (original): The system of claim 19 wherein the first material comprises polyethylene.

Claim 21 (original): The system of claim 19 wherein the first material is not tacky at temperatures below the predetermined temperature.

Claim 22 (withdrawn): A method of retaining a stent on a balloon comprising:
mounting the stent onto the balloon, the balloon including an inner layer and an outer layer covering only a limited portion of the inner layer, the stent including gaps, the stent covering at least 55 percent of the balloon;

sheathing the mounted stent and balloon with a sheath;

heating the mounted stent and balloon; and

flowing an outer layer of the balloon into the gaps formed in the stent while an inner layer of the balloon does not flow, and while the balloon is heated.

Claim 23 (withdrawn): The method of claim 22 wherein heating the balloon comprises elevating the balloon temperature to a temperature of about 50 to 70 degrees Celsius.

Claim 24 (withdrawn): The method of claim 22 wherein the outer layer flows into a predetermined gap arrangement.

Claim 25 (withdrawn): The method of claim 22 wherein the outer layer flows into a random gap arrangement.

Claim 26 (withdrawn): The method of claim 22 further comprising pressurizing the balloon.

Claim 27 (cancelled).

Claim 28 (withdrawn): The method of claim 22 further comprising:
cooling the heated stent assembly; and

removing the sheath from the cooled assembly.

Claim 29 (withdrawn): A balloon stent assembly system comprising:

a balloon including an outer first layer and an inner second layer, the outer first layer covering only a limited portion of the inner second layer;

a stent disposed on the balloon; and

a sheath disposed on the stent and the balloon,

wherein the outer first layer flows into gaps formed in the stent when the balloon stent assembly is heated to a predetermined temperature, and retains the stent on the balloon during intravascular movement and the inner second layer does not flow into the gaps, and wherein the sheath is removed after cooling the heated stent assembly from the predetermined temperature.

Claim 30 (original): The apparatus of claim 1 wherein the stent covers at least 55 percent of the outer first layer.

Claim 31 (withdrawn): The apparatus of claim 1 wherein the sheath is placed around the balloon to maintain a limited inflation size.

Claim 32 (withdrawn): The apparatus of claim 31 wherein the apparatus is configured to allow removal of the sheath after the apparatus has been heated to the predetermined temperature and allowed to cool to room temperature.

Claim 33 (withdrawn): The method of claim 23 further comprising:

pressurizing the balloon while heating the balloon.

REMARKS/ARGUMENTS

Claim 1 has been amended. Support for the amendment made to claim 1 may be found throughout the specification, such as at paragraph [0019]. No new matter has been added. Reconsideration of this Application and entry of this Amendment are respectfully requested. Upon entry of this Amendment, claims 1, 2, 4-26, and 28-33 are pending, with claims 22-26, 28, 29, and 31-33 withdrawn from consideration at this time.

35 U.S.C. §102(b) Rejections

In the Office Action dated February 14, 2007, claims 1, 4-10, 12, 14, 17-21, and 30 were rejected under 35 U.S.C. §102(b) as being anticipated by Yan (U.S. Patent No. 6,066,156). Applicant respectfully traverses this rejection.

As an initial matter, Applicant respectfully points out that Yan has been substantively addressed in previous responses to Office Actions during prosecution of this application. Specifically, amendments made to the claims overcame rejections based on Yan. *See* Amendment After Final filed on January 3, 2005, and Request for Continued Examination filed on March 1, 2005. As discussed in further detail below, the pending claims are patentable over Yan.

Independent claim 1 recites an apparatus for treating a vascular condition that includes “a balloon including an outer first layer and an inner second layer, the outer first layer covering only a limited portion of the inner second layer; and a stent disposed on the outer first layer of the balloon.” As recited by claim 1, “the outer first layer flows into gaps formed in the stent when the apparatus is heated to a predetermined temperature, and retains the stent on the balloon during intravascular movement and the inner second layer does not flow into the gaps.” Yan does not disclose or suggest each and every feature of claim 1.

Yan discloses different embodiments of mounting a stent to a balloon. In one embodiment, the balloon (14) is coated with a heat sensitive adhesive (16), the adhesive is heated to a temperature above the glass transition temperature, and the stent (18) is then mounted to the balloon (14). *See* Yan at col. 6, lns. 49-52; FIG. 1. Once the temperature has been lowered to a level that is below the glass transition temperature, the stent is secured to the balloon. *See* Yan at col. 6, lns. 55-58. The change in temperature is used to alter the tackiness of the adhesive. *See* Yan at col. 6, lns. 42-58. Yan does not disclose or suggest that the adhesive that is already on the balloon flows into gaps formed in the stent. In another embodiment, the

stent is first crimped onto the balloon, and then adhesive is applied so that the adhesive fills the gaps (15) between the struts of the stent. *See* Yan at col. 6, ln. 66 – col. 7, ln. 3; FIG. 3. Yan expressly teaches that in this embodiment, there is no adhesive between the stent and the balloon. *See* Yan at col. 7, lns. 3-7. This is because the adhesive is applied after the stent has been crimped onto the balloon. The outer layer of the balloon on which the stent is disposed does not “flow into the gaps formed in the stent when the balloon stent assembly is heated to a predetermined temperature,” as recited by claim 1.

In view of the foregoing, Applicant respectfully submits that claim 1 and the claims that depend from claim 1, and include additional advantageous features, are patentable over Yan, and respectfully request that the rejection to claims 1, 4-8, and 30 be withdrawn.

Independent claim 9 recites a balloon stent assembly system that includes “a balloon including at least one non-tacky outer layer and at least one inner layer, the non-tacky outer layer covering only a limited portion of the at least one inner second layer; and a stent disposed on the outer layer.” As recited by claim 9, “when the balloon is heated at a predetermined temperature the outer layer flows into gaps formed in the stent while the inner layer does not flow.” Yan does not disclose or suggest each and every feature of claim 9.

Yan is discussed above. In the embodiment of Yan that teaches applying adhesive in between the struts of the stent, the adhesive is applied after the stent is crimped onto the balloon so that there is no adhesive between the stent and the balloon. *See* Yan at col. 6, ln. 66 – col. 7, ln. 7. In the embodiment of Yan that teaches mounting the stent on a layer of heat sensitive adhesive, there is no teaching or suggestion that the adhesive flows into the gaps formed into the stent. Moreover, the adhesive of Yan does not provide a non-tacky outer layer, as recited by claim 9.

In view of the foregoing, Applicant respectfully submits that claim 9 and the claims that depend from claim 9, and include additional advantageous features, are patentable over Yan, and respectfully request that the rejection to claims 9, 10, 12, 14, and 17-21 be withdrawn.

35 U.S.C. §103(a) Rejections

In the Office Action, claims 2, 11, 13, 15, and 16 were rejected under 35 U.S.C. §103(a) as being unpatentable over Yan. Applicant respectfully traverses this rejection.

Claim 2 depends from independent claim 1, and claims 11, 13, 15, and 16 depend from independent claim 9. As discussed above, claims 1 and 9 are patentable over Yan, because Yan does not disclose or suggest each and every feature of claims 1 and 9.

Moreover, *In re Aller*, which was cited by the Examiner on page 4 of the Office Action, does not apply to the facts of this case, because the “general conditions” of the claims are not disclosed by Yan. *See* MPEP §2144 (the facts of the prior legal decision must be “sufficiently similar” to the application being examined). Yan does not disclose any temperature to which the stent delivery catheter is heated wherein the outer first layer flows into gaps formed in the stent. The temperatures cited by Yan are related to the transition of the adhesive between tacky and non-tacky adhesive states, and the temperatures are well below the temperature range recited by claims 2 and 16. *See* Yan at col. 3, lns. 46-64.

With regard to claims 11, 13, and 15, Yan is completely silent as to stent retention forces. As such, Yan does not disclose the “general conditions” of claims 11, 13, and 15.

In view of the foregoing, Applicant respectfully submits that claims 2, 11, 13, 15, and 16 are patentable over Yan, and respectfully request that the rejection to claims 2, 11, 13, 15, and 16 be withdrawn.

Conclusion

For the foregoing reasons, Applicant believes all the pending claims are in condition for allowance and should be passed to issue. The Commissioner is hereby authorized to charge any additional fees which may be required under 37 C.F.R. §1.17, or credit any overpayment, to Deposit Account No. 01-2525. If the Examiner feels that a telephone conference would in any way expedite the prosecution of the application, particularly in view of the long pendency of the application, please do not hesitate to call the undersigned at telephone (707) 543-0221.

Respectfully submitted,

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